



Closing the Quality Gap: Revisiting the State of the Science

**End-of-Life and Hospice Care** 

**Evidence-based Practice Center Systematic Review Protocol** 

## I. Background and Objectives for the Systematic Review

The Agency for Healthcare Research and Quality (AHRQ) has requested a systematic review on end-of-life and hospice care as part of the 2011 Closing the Quality Gap: Revisiting the State of the Science (CQG) series. This series is a continuation of the 2004 CQG series, which performed a critical analysis of the existing literature on quality improvement (QI) strategies for a selection of disease and practice priority areas for transforming health care quality. The focus of the series is translating research into practice—identifying those activities that increase the rate with which practices known to be effective are applied to patient care in real-world settings. In other words, the series aims to facilitate narrowing of the "quality gap" that is in large part responsible for suboptimal health care practices and outcomes. The 2011 CQG series continues this work with reviews in a new set of priority areas for improving quality.

The 2011 CQG series will address three dimensions of quality: measuring (or providing information on quality), influencing (or incentives for better-quality care), and improving (addressing quality infrastructure). For end-of-life care, since other current projects are currently focusing on quality measurement and since there is little research and few interventions at a policy or regulatory level, the review will focus on QI where there is a rich and growing literature. As in the previous CQG series, <sup>12</sup> we define QI strategies as interventions aimed at reducing the quality gap (the difference between health care processes or outcomes observed in practice and evidence-based practices potentially obtainable on the basis of current professional knowledge).

For the purpose of this review, we will address the three interrelated areas of palliative care, end-of-life care, and hospice care. Palliative care is defined as medical care focused on improving the quality of life of people facing serious or life-threatening illness, including the end of life. It is often provided as a service or QI intervention and can be delivered in any setting. Emphasis is placed on pain and symptom management, communication, and coordinated care. End-of-life care is defined as care delivered to dying patients, and it is a small subset of palliative care. Hospice is also a subset of palliative care: a care delivery system and insurance benefit for patients in the last months of life who have chosen quality of life as the primary goal of care that is provided primarily in certain settings (in the United States, these settings include the home, special inpatient units, and nursing homes). Since end-of-life care and hospice care are both subsets of palliative care, we will refer to the focus of this review as "palliative care" throughout this protocol, recognizing that end-of-life care and hospice care are both included.

The purpose of QI in palliative care is to improve care to maximize the quality of life of people facing serious illnesses and the end of life and of their families. This includes relief from physical and psychosocial symptoms; psychosocial and spiritual support for both the patient and his or her family members and other caregivers; excellent communication about topics such as prognosis; person-centered care, with compassion, personalization, and cultural sensitivity; care planning and prevention of crises; and opportunities for comfortable dying, life closure, and

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control of the circumstances of death.

Extensive evidence and numerous interventions are available for the various domains in palliative care. For example, many types of medications and other interventions to treat pain are supported by strong evidence,<sup>3</sup> and guideline-based pain treatments can lead to significant reductions in pain severity and improvements in pain-related outcomes such as quality of life.<sup>4</sup> However, studies have found that these medications and other interventions are often not well integrated into medical practice. For example, for the domain of communication, in a study of audiotaped initial oncology consultations for patients with terminal cancer, fewer than half of oncologists offered alternatives to chemotherapy as an option. In addition, only 58 percent of patients were informed of their life expectancy, and only 60 percent were aware of uncertainty about the benefit of chemotherapy. For the domain of pain, despite proven guidelines—such as the World Health Organization's three-step analgesic ladder, which gradually adjusts the potency of medication as the patient's level of pain increases—pain continues to be undertreated, particularly among vulnerable populations such as nursing home patients. In 2009, only 42 percent of patients who died in the United States received any hospice care, and half of patients who did receive hospice care received fewer than 3 weeks of care.

Variation in quality also exists within hospice programs, which are specifically focused on end-of-life care. In the Family Evaluation of Hospice Care survey conducted by the National Hospice and Palliative Care Organization, family members of general hospice patients who had cancer and other illnesses completed a questionnaire after their relatives died. The survey results showed that 18.2 percent of family members noted problems with inattention to their needs for support (variation among hospices, 25th and 75th percentiles, 12.6% and 21.4%), and 9.8 percent of family members reported that their need for emotional support was unmet (25th and 75th percentiles among hospices, 5.4% and 13.3%). Current approaches to providing palliative care or improving quality in key domains at the end of life (e.g., the domains of communication and pain) vary widely, and there clearly is a need for information on what types of QI interventions can improve the quality of palliative care for patients. Although there have been a number of systematic reviews related to this topic, recent ones have focused mainly on palliative care and hospice interventions and on specific domains, settings, or populations (e.g., communication, intensive care unit [ICU], cancer); none of them have considered QI strategies. Based on our experience and the results of a brief initial survey of the literature, we did not identify any reviews with a specific QI perspective (or evaluation of which specific types of QI interventions are effective in which domains or settings) nor any evaluation of the different domains addressed within QI (such as cancer pain). Reviews have also focused on studies with outcomes, not on implementation studies of the feasibility of QI—although there are some of these studies in the literature. No reviews have addressed QI within the hospice or nursing home setting specifically—although some nursing home studies are included in existing reviews. There are some studies of different types of QI interventions (case management, order sets, and improvement of communication) that are not specifically addressed in these reviews. There also are some nationwide or provincewide system change studies and new clinical trials and QI interventions, especially in the area of cancer pain, that are relevant to palliative care more broadly. Although there is little literature specifically in the area of hospice care, much of the broader palliative care literature is potentially applicable to this setting, particularly in domains such as cancer pain and communication.

Recent studies have found that a wide variety of QI and intervention studies have shown effectiveness for palliative care overall and for specific domains in a variety of settings and





populations. There are a wide variety of types of QI interventions, such as case management, provider and patient education, targeted patient interventions (such as assistance with developing questions to ask), structured order sets, and patient screening for eligibility for palliative care services or specific needs (such as pain management). For hospice care, although providers are now required by the Center for Medicare and Medicaid Services to have a quality assurance program with a QI component, little systematic information is available on which types of interventions work.

A consensus report published by the Improving Palliative Care in the Intensive Care Unit group in September 2010 noted that there are "...two main models for intensive care unit—palliative care integration: (1) the 'consultative model,' which focuses on increasing the involvement and effectiveness of palliative care consultants in the care of intensive care unit patients and their families...and (2) the 'integrative model,' which seeks to embed palliative care principles and interventions into daily practice by the intensive care unit team for all patients and families facing critical illness." The consensus report listed multiple examples of consultative versus integrative palliative care initiatives for ICU patients, but noted that it is unclear which "...structure of a palliative care initiative...can best meet the needs of ICU patients, their loved ones, clinicians, and the hospital." A complete systematic review of these initiatives with initiative classification as primarily "integrative" or "consultative" could determine which model is more efficacious and would be applicable to most settings outside the ICU, as well as where palliative and other medical services could work together. From a comparative effectiveness perspective, understanding in what circumstances each model is best supported by the evidence can help practitioners choose which model to adopt in particular situations.

We therefore propose a systematic review that fills key gaps in existing reviews; crosses domains, populations, and settings; and applies a broader QI framework to the field of palliative care. This approach will provide additional insights into what interventions are effective, develop knowledge of the application of QI principles in this field, and define key gaps for further intervention research.

We discussed areas of focus, which included a number of stakeholder perspectives, with the Technical Expert Panel (TEP). These included researchers in the field of hospice and palliative care; representatives of different disciplines (e.g., social work, nursing) and from key settings (nursing home, hospice, and intensive care); and payers. Additional audiences who might also find value from the report include professionals in both palliative care and hospice programs, as well as those in other settings with a significant percentage of patients who have serious and advanced disease, such as cancer centers, medicine inpatient units, and nursing homes. Other potential audiences include members and staff of health care professional organizations (e.g., the Academy of Hospice and Palliative Medicine, the Hospice and Palliative Nurses Association; key funders in this area (e.g., the National Cancer Institute); and staff of organizations investing in palliative care QI and systems initiatives (e.g., the Center for Medicare and Medicaid Services, the Veterans Health Administration, Kaiser Permanente, the Institute for Healthcare Improvement). Researchers in palliative care and relevant fields, as well as relevant policymakers (e.g., the National Quality Forum's National Priorities Partnership<sup>11</sup>) and the members and staff of advocacy groups (e.g., the American Cancer Society) will also be able to use the contents of the review. Finally, we plan to frame and structure our review so that it relates to the broader QI literature, the CQG series, and the needs of the broader community of OI practitioners and researchers.

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The framework below (Figure 1) shows the literature in palliative care as a grid, with different populations, domains of care, targets of QI, settings (and integrated care), conditions, and categories of QI relevant to palliative care. The targets show the areas where a QI intervention might focus—such as an intervention specifically targeting pain management in patients with advanced disease. Underlined areas show the targets for which we will set priorities for the first Key Question (KQ), based on our initial literature survey and the needs of key audiences. Other targets will be addressed in the second KQ, since many palliative care interventions are multidimensional; however, this KQ will focus on particular types of QI interventions and settings. This approach will help us to concentrate on key areas and will allow us to make the results of our review both focused enough so that we can draw clear conclusions and relevant enough to QI initiatives while still addressing all key targets, settings, conditions, and types of QI at least in part. So, for example, in our focus on cancer pain we will address all settings of care; and in our focus on communication, we will specifically address the different categories of QI interventions. We will also conduct focused searches and separate analyses for QI studies in hospice care and nursing homes, addressing all potential QI targets.

### **II. The Key Questions**

### **Question 1**

What is the effectiveness of QI interventions for key targets of QI and settings relevant to palliative care?

- a. Specific targets of QI: What is the effectiveness in terms of processes and outcomes for pain; communication; continuity, coordination, and transitions; and patient and family distress in palliative care populations? (See column 3 in Figure 1 for a listing of targets of QI.)
- b. Specific settings: What is the effectiveness for QI interventions in any domain of palliative care within hospice programs or nursing homes?

### **Question 2**

What is the evidence for different QI models for improving palliative care in the domains of pain and communication, with a focus on patients with advanced cancer?

- a. What is the evidence for different types of QI interventions? (See "Interventions" below and column 5 of Figure 1.)
- b. What is the evidence for different models in palliative care: structural, integrative, compared with consultative? (See "Comparators" below and column 5 of Figure 1 for definitions.)

### **PICOTS Framework**

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The following elements of the PICOTS framework apply to both KQs 1 and 2:

### **Population(s)**

For the purposes of this review, we will define the relevant population as "...seriously ill patients and those with advanced disease (such as persons living with advanced cancer or intensive care unit patients at high risk of dying), who are unlikely to be cured, recover, or stabilize" (this definition is adapted from the National Consensus Project<sup>12</sup>). The review will cover the entire lifespan, including pediatric and geriatric populations. Outcomes related to families and caregivers of these patients (e.g., depressive symptoms of family members of ICU patients) will also be included. We will include patients with all conditions meeting the population definition (e.g., heart failure, end-stage lung disease, dementia, and frailty). Given that much of the literature in this field is about cancer and that interventions for cancer pain have much stronger evidence than for other conditions, we will conduct additional searches in this area (e.g., patients with advanced, metastatic, or incurable cancer).

#### **Interventions**

For both KQs, we will use the CQG series definition of QI: "[A]ny tool or process aimed at reducing the quality gap for a group of patients typical of those seen in routine practice." For KQs 1 and 2a, we will begin with the CQG taxonomy (listed below) of QI interventions:

- Physician reminder systems (such as prompts in paper charts or computer-based reminders).
- Facilitated relay of clinical data to providers (patient data transmitted by telephone call or fax from outpatient specialty clinics to primary care physicians).
- Audit and feedback (physician performance tracking and reviews, using quality indicators and reports, comparisons with national/State quality report cards, publicly released performance data, and benchmark outcomes data).
- Physician education (workshops and professional conferences, educational outreach visits, and distribution of educational materials).
- Patient education (classes, parent and family education, pamphlets and other media, etc.).
- Promotion of self-management (workshops and materials such as blood pressure or glucose monitoring devices).
- Patient reminder systems (telephone calls or postcards from physicians to their patients).
- Organizational changes (total quality management or continuous QI programs, multidisciplinary teams, shifting from paper-based to computer-based recordkeeping, and long-distance case discussion between professional peers).
- Financial incentives, regulation, and policy (performance-based bonuses and alternative reimbursement systems for physicians, positive or negative financial incentives for patients, and changes in professional licensure requirements).

OI intervention types that we anticipate will be particularly prevalent are listed in the Analytical Framework (see column 5 in Figure 1 under "Closing the Quality Gap Categories". We will adapt these categories or add to them as needed to fit the palliative care literature. For





example, in "facilitated relay of clinical data," we will also include structured communication interventions. For the QI target of distress, we will include social work/psychosocial care and bereavement in order to address interventions relevant to the interdisciplinary nature of palliative care.

For KQ 2, we will examine structural, integrative, and consultative models of care as described in the Analytic Framework (see column 5 in Figure 1).

### **Comparators**

For KQ 1, we will abstract the type(s) of QI interventions used in each article and compare evidence for effectiveness across types of interventions. KQ 2 addresses the comparison of structural models (e.g., policy or health care—system changes), integrative models (embedding palliative care principles and interventions into daily practice, such as provider education or organizational strategies), and consultative models (using or increasing the use and effectiveness of additional services, such as palliative care consultants) of improving palliative care. 10 We will categorize all relevant interventions into one of these QI models and compare the evidence for effectiveness across them.

### **Outcomes measures for each KQ**

For both KQs, we will include all relevant patient or family/caregiver outcomes, focusing on interdisciplinary care. These outcomes include:

- Patient and family satisfaction/perceptions of palliative care.
- Patient symptoms, needs, distress, and quality of life.
- Health care utilization, such as hospital admissions or do-not-resuscitate orders (but not costs).
- Quality of care measures, such as timeliness of response to pain and other symptoms.
- Family/caregiver psychosocial symptoms, support, needs, quality of life, and grief/bereavement.

We will exclude studies that did not report measurements of any of these outcomes or that only have outcomes not related directly to the target populations (e.g., staff knowledge, advance directive completion rates).

### **Timing**

We will include any timing of followup, including after-death interviews with families/caregivers.

### **Settings**

We will address all settings, both inpatient and outpatient, with a specific focus on the nursing home setting (primary) and home hospice program setting (specialty), as underlined in





the Analytic Framework (see column 4 in Figure 1). We will also address QI interventions that occur within inpatient or outpatient palliative care programs.

## **III. Analytic Framework**

The attached framework (Figure 1) is derived from the National Quality Forum palliative care framework and a recent consensus project conducted to develop a framework for end-of-life cancer quality measurement. 11 13 The framework shows the literature in end-of-life care as a grid, with different populations, domains of care, targets of QI, settings (and integrated care), and categories of QI relevant to palliative care. Underlined areas show where we will prioritize the searches and review, but all areas in the framework will be included.





Figure 1: Framework for end-of-life and hospice care systematic review

1.Population definition for EOL Quality Improvement	2. Domains (1,2) of EOL Quality Improvement	3. Targets for EOL Quality Improvement	4. Settings	5. Types of quality improvement interventions
NCP's definition of palliative care adapted <sup>(0)</sup> :  Seriously ill patients and those with advanced disease (such as persons living with advanced cancer or intensive care unit patients at high risk of dying), who are unlikely to be curred, recover or stabilized, and their caregivers.  Conditions: Cancer Heart failure End-stage lung disease Dementia Frailty	Structure Processes Physical  Psychological & Psychiatric  Social  Spiritual, Religious, & Existential  Cultural  Care of Imminently Dying  Ethical and Legal  Other	Interdisciplinary teams Case management Interdisciplinary assessment  Pain Dyspnea Nausea Vomiting Fatigue Distress Delirium Depression Psychosocial support for families  Family support/ caregiving  Value / Meaning  Cultural assessment  Prognosis discussion/ documentation Comfort care Advance care planning Communication/Decisionmaking Continuity/Coordination/Transitions Use of technology / Overutilization Staff distress, competence, retention Patient safety: Falls	Settings: Hospice Nursing home Outpatient (primary care, oncology) Inpatient Intensive care Integrated	Structural -Institutional/local policies Integrative: embed palliative care principles and interventions into daily practice - Provider education - Organizational strategies  Consultative: increasing the use and effectiveness of palliative care consultants/other nonintegrative interventions - Triggering criteria Scope of consultation Quality of consultation services <sup>3</sup> Closing the Quality Gap categories of quality improvement, particularly: -Patient-centered interventions (education, self-management) - Facilitated relay of clinical data to providers - Financial incentives, regulation, and policy

- 1. National Consensus Project for quality palliative care. Clinical practice guidelines for quality palliative care. Pittsburgh, PA, 2004. www.nationalconsensusproject.org
- 2. National Quality Forum. A national framework and preferred practices for palliative and hospice care quality. Washington, DC, 2006. www.qualityforum.org
- 3. Adapted from: Nelson JE, Bassett R, Boss RD, Brasel KJ, Campbell ML, Cortez TB, Curtis JR, Lustbader DR, Mulkerin C, Puntillo KA, Ray DE, Weissman DE; Improve Palliative Care in the Intensive Care Unit Project. Models for structuring a clinical initiative to enhance palliative care in the intensive care unit: a report from the IPAL-ICU Project (Improving Palliative Care in the ICU). Crit Care Med. 2010 Sep;38(9):1765-72.

Abbreviations: EOL = end of life; NCP = National Consensus Project.

Source: <u>www.effectivehealthcare.ahrq.gov</u>





### IV. Methods

### A. Criteria for Inclusion/Exclusion of Studies in the Review

We will include studies on seriously ill patients and those with advanced disease, including studies on pediatric and geriatric populations. We will also include studies with outcomes related to the families/caregivers of these patients. Although patients with all conditions (e.g., heart failure, end-stage lung disease, dementia, and frailty) will be included, we will specifically focus on patients with cancer (patients with advanced, metastatic, or incurable disease), given the richness of the literature for this condition.

Since there are a number of high-quality studies in this field (e.g., randomized trials and prospective interrupted time series), we will exclude all retrospective and uncontrolled studies of QI interventions. We will exclude individual studies published before 2000 because the nature of both QI and palliative care practice has changed substantially since that time; palliative care has existed as a specialty and service only since 2000, and the populations served by hospice care were also markedly different before 2000. In addition, the pre-2000 data have been thoroughly addressed in a previous AHRQ Evidence-based Practice Center (EPC) report<sup>14</sup> and an extensive National Institute for Clinical Excellence (United Kingdom) report.<sup>14 15</sup> We will reference previous systematic reviews that addressed the pre-2000 literature, including key intervention studies included in those reviews. We will not limit our search to only English-language studies, since a significant proportion of the palliative care QI studies have been conducted in Europe. If we identify a potentially eligible study not published in English, we will attempt to have it screened by an interpreter.

# B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies To Answer the Key Questions

- MEDLINE (via PubMed)
- PsycINFO
- CINAHL
- The Cochrane Library (including the Cochrane CENTRAL Register of Controlled Trials)
- DARE Database of Systematic Reviews

Comprehensive search strategies will be developed through an analysis of studies known to be eligible for this review and related systematic reviews. These strategies will combine controlled vocabulary terms (e.g., MeSH, EMTREE terms) with free-text terms. As an example, our preliminary search strategies are provided in Appendix 1. We will scan the reference lists of all articles included for data abstraction as part of a hand-searching process. We will also scan reference lists provided by internal experts (the team), the TEP, and AHRQ. For key intervention studies that the team, TEP, or AHRQ is aware of that have been accepted for publication but not

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yet published, the team will contact the author for permission to review the version for publication and to include it in this review.

Searches will be completed on a specified date, and the results of these searches will be downloaded to the ProCite® (Thomson Reuters, New York, NY) reference database. An updated search will be run during the peer review period. The articles identified by the updated searches will be added to our reference database and will be screened and abstracted in the same manner as the articles identified in the original search strategy.

All additional articles identified by the reviewers will be evaluated by the principal investigator to determine if they are eligible for this review. If eligible, the core team will determine if the article was captured in the original search. If not captured, we will evaluate why the article in question was not captured in the search strategy. If the article was captured in the original search, the principal investigator will determine what measures need to be taken to determine if other eligible articles were not included.

### C. Data Abstraction and Data Management

The Evidence-based Practice Center investigators will use DistillerSR software (Evidence Partners Incorporated, Ottawa, Canada) to manage the screening only of articles identified in the database searches. All applicable citations identified by the search strategies are uploaded to the system and managed in the following manner:

- 1. Abstract screening: Each title and abstract is reviewed by two independent reviewers. Both reviewers must agree about whether or not an abstract is eligible. If there is disagreement between the two reviewers, the following protocol will be followed:
  - The reviewer who indicated that the article is eligible for the next level of review will first re-evaluate his/her answer. If he/she agrees that it should be excluded, he/she will change the answer in the systematic review online system and the conflict will be resolved.
  - b. If the first reviewer (above) believes that the article is eligible for the next level of review, he/she will contact the second reviewer and give the rationale for inclusion. The second reviewer will re-evaluate his/her answer. If he/she agrees with reviewer 1, he/she will change the answer in the the Distiller program system.
  - If the first and second reviewers (above) cannot come to an agreement, the abstract will be discussed at a meeting of all investigators.
- 2. Full-text article screening: The review protocol for this level is the same as for the abstract inclusion/exclusion level.
- 3. Data abstraction: Eligible articles will be sent for data abstraction. We will develop more detailed definitions for the types of palliative care interventions (consultative vs. integrative) and pilot test and refine them to improve the reliability of abstracting data in these categories. We will create table skeletons to abstract data directly from the

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articles into evidence tables. We will use either Microsoft ACCESS or EXCEL to manage this portion of the review. We will abstract details about the study design and conduct and about the population, intervention(s) and outcomes in order to answer the KQs.

### D. Assessment of Methodological Quality of Individual Studies

The review of eligible studies to assess the risk of bias or methodological quality is very important. The elements of critical appraisal were determined by both methodologists and clinicians, since study design features and relevant clinical measurements may influence the risk of bias. Our approach is to involve both methodologists and clinicians with the investigative team in the construction of explicit criteria and in the appraisal of studies.

During the review of individual studies we will complete our critical appraisal. Instruments designed for specific study designs will be used along with the quality tools previously used by our EPC. We plan to use tools implemented successfully in past EPC projects, including the Cochrane Collaboration Tool for Assessing Risk of Bias from the Cochrane Handbook for Systematic Reviews of Interventions for assessing randomized controlled trials 16 and the Newcastle-Ottawa Scale for assessing the risk of bias of the reported data in both cohort and case control studies.<sup>17</sup>

We will assess the risk of bias and appropriateness of all studies that meet our eligibility criteria, following the guidance contained in chapter 6 of the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews (hereafter, Methods Guide). 18 We will use a limited number of key criteria that are most appropriate for each study design and that are most important for determining the validity of the studies. After the pool of included articles in this review is determined, the core team of investigators will determine if the Cochrane Collaboration tool<sup>16</sup> or the Newcastle-Ottawa Scale<sup>17</sup> need to be altered for this particular project. Since the EPC team is looking at a unique population in a very limited setting, we will likely need to alter these tools by tailoring them to our particular population. If necessary, we will add criteria to assess unique aspects of the conduct of studies on a given topic. The quality of individual studies will be classified as "good," "fair," or "poor" based on the degree to which the studies adhere to the defined criteria. We will also assess other elements of study design that affect the applicability of the studies. Generally, a "good" study at least partially fulfills all criteria. A "fair" study does not meet at least one important criterion or generally meets most criteria but has a major flaw. A "poor" study does not meet most criteria or has a fatal flaw. For randomized controlled trials, important criteria include randomization method, allocation concealment, blinding or masking, dropouts and withdrawals, and method of statistical analysis (intention to treat).

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### E. Data Synthesis

We intend to describe the information we abstract in a systematic manner, but it is not our intention to conduct any meta-analyses.

If, during the course of this review, we find large bodies of literature that address common outcomes and in similar populations and settings, we will consider conducting meta-analyses. We plan to conduct subgroup analyses for hospice care and for nursing home settings.

### F. Grading the Evidence for Each Key Question

At the completion of our review, we will assess the quantity, quality, and consistency of the body of available evidence addressing KQs 1 and 2. We will use an evidence grading scheme recommended by the GRADE Working Group, which has been adapted by AHRQ in its Methods Guide<sup>18</sup> and published in the Journal of Clinical Epidemiology. <sup>19</sup> We will consider the strength of the study designs, with randomized controlled trials having the highest level of evidence. followed by observational studies. If an outcome is evaluated by at least one randomized controlled trial in addition to observational studies, our evidence grade will be based on the randomized controlled trials, followed by the quality of the cohort studies. If an outcome has not been evaluated in any randomized controlled trial, our evidence grade will be based on the best available observational study.

We will assess the strength of the best available evidence, including the risk of bias in relevant studies, as well as aspects of consistency, directness, and precision as described in the Methods Guide. 18,19 For each outcome of interest, two investigators will grade the major outcomes for each KQ, and then the entire team will discuss their recommendations and reach consensus.

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### G. Applicability

To assess applicability, we will use criteria stipulated in the Methods Guide<sup>18,20</sup> and input from the TEP concerning what criteria would be most useful to stakeholders. We will address applicability in two ways. First, we will assess studies to ensure that they included a relevant palliative care population and outcome, as defined in the section on KQs. For example, an intervention to improve advance directive completion by healthy patients might not translate well for ill cancer patients. An outcome of improved adherence to chemotherapy may not necessarily translate into improved quality of life. Secondly, to evaluate applicability for included studies, we will extract the relevant patient population (cancer type, stage, etc.) and setting (size, teaching vs. community hospital, etc.) information from each study in the evidence tables. For example, a QI study on improving pain management in cancer patients may not translate well to the frail elderly, for whom the treatment of pain is very different. A OI study that is successful in a hospital setting likely will not translate well to the nursing home setting. Finally, we will abstract any comments in the article about feasibility or setting-specific issues that may be relevant to translation to other settings.

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### VI. Definition of Terms

There are two main types of quality improvement models in palliative care. "Consultative" models focus on increasing the involvement and effectiveness of palliative care consultants in the care of patients and their families, while "integrative" models seek to embed palliative care principles and interventions into daily practice by the usual care unit team for all patients and families. 10

## **VII. Summary of Protocol Amendments**

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

## VIII. Review of Key Questions

For all EPC reviews, key questions will be reviewed and refined as needed by the EPC with input from the Technical Expert Panel (TEP) to assure that the questions are specific and explicit about what information is being reviewed.

## IX. Technical Experts

Technical Experts comprise a multidisciplinary group of clinical, content, and methodological experts who provide input in defining populations, interventions, comparisons, or outcomes as well as in identifying particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicted opinions are common and perceived as health-scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design, and/or methodological

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approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and recommend approaches to specific issues as requested by the EPC. Technical Experts do not do analysis of any kind or contribute to the writing of the report. They have not reviewed the report, except as given the opportunity to do so through the public review mechanism

Technical Experts must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Individuals are invited to serve as Technical Experts because of their unique clinical or content expertise, and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

### X. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodological expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will, for CERs and Technical briefs, be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than \$10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.